

## **DETAILED ACTION**

### ***Reissue Applications***

1. Claims 7-9 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows:

Claim 7, line 1: "upper airway disorders"

Claim 7, line 3 and 4: "distending force".

These limitations are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe the broad range of "upper airway disorders"; rather, the specification is limited to sleep apnea. The specification further does not describe the broad "distending force"; rather, the specification is limited to vacuum-type force application.

2. The amendments filed from 4/18/2003 to 8/2/2007 propose amendments to the claims that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required. Claim amendments filed from 4/18/03 to 8/2/07 have been made relative to amendments filed on this reissue application instead of patented claims. See for instance: Newly added claims 7-9 are not underlined and have incorrect claim identifiers. All claim amendment must be made relative to issued patent claims instead of prior version of amended claims. (See MPEP 1453).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 7 recites "applying a distending force on such a patient's neck". The specification does not convey possession of broadly applying a distending force (for example mechanical, spring-type force) because the specification is limited to the application of vacuum pressure to distend the body.

5. Additionally, there is evidence that Mr. Sanders did not have possession of this later claimed subject matter at the time of filing (6/8/1992). In the declaration of Mr. Eugene Scarberry (filed in Attachment A of Mark Sanders' declaration dated 12/13/1999) statement 4 indicates that "On or about July 14, 1995, I became aware that Kingman Strohl, who is a medical consultant to Respirolic, Inc., had suggested the possibility that a spring biased apparatus, similar in concept to an enlarged Breathe Right <sup>TM</sup> brand nasal strip, could be adhesively affixed to frontal portions of patient's neck to draw outward or distend adjacent neck tissue . . . " (emphasis added). It is quite clear from this statement that, the limitation "distending force" is intended to embrace "a

spring biased apparatus" noted by Mr. Strohl to Mr. Scarberry, among other distending force means. Mr. Scarberry's statement also demonstrates that Mr. Sanders did not have possession to this later claimed subject matter at the time of filing which is 6/8/92.

6. In a declaration filed by Mr. Sanders dated 12/13/99, Mr. Sanders cited column 9 lines 28-36 of Patent '878 as having broadly disclosed the presently claimed subject matter. Contrary to Mr. Sanders' assertion, the cited passage fails to remotely disclose this later claimed subject matter. In fact, this passage clearly indicates "the application of negative pressure" (col. 9 lines 28-31). There is nothing in this passage or any passages in applicant's original disclosure which remotely suggest that applicant has in possession of broadly using "distending force" such as a spring biased apparatus to distend a portion of patient's neck at a filing date of 6/8/92.

7. In addition, the specification does not describe "treating" the so-called "upper airway disorders" (emphasis added) in a way as to reasonably convey possession of the claimed invention. In particular, upper airway disorders are not described, with the exception of sleep apnea.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what forms of respiratory disorder (apart from sleep apnea) are included in the term "upper airway disorders".

***Specification***

10. The specification filed 12/13/1999 is objected to for failing to comply with 37 CFR 1.173 which requires applicant to submit the entire specification. Examiner considers the entire specification to include the drawings.

11. This application is a continuation of a reissue application 08/702,107 filed on 08/23/96. The first page of the specification does not include a statement cross-referencing the parent reissue application '107. (See MPEP 1451 and 37 CFR 1.177 (a)).

***Supplemental Declaration***

12. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-3 and 7-9 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

See MPEP § 1414.01.

***Consent of Assignee***

13. This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

14. This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest in order to support the consent to a reissue application required by 37 CFR 1.172(a). The assignee's ownership interest is established by:

(a) filing in the reissue application evidence of a chain of title from the original owner to the assignee, or

(b) specifying in the record of the reissue application where such evidence is recorded in the Office (e.g., reel and frame number, etc.).

The submission with respect to (a) and (b) to establish ownership must be signed by a party authorized to act on behalf of the assignee. See MPEP § 1410.01.

An appropriate paper satisfying the requirements of 37 CFR 3.73 must be submitted in reply to this Office action.

This must be signed by the inventor(s) NOT the assignee because this is a broadening application.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./  
Examiner, Art Unit 3774

/DAVID ISABELLA/  
Supervisory Patent Examiner, Art Unit 3774